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|--|-------------|----------------------|-------------------------------|------------------|
| APPLICATION NO.                                    | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
| 10/821,679   | 04/08/2004  | Barrie Tan           | BT-002                        | 1383             |
| 38051  | 7590        | 03/27/2007           |                               |                  |
| KIRK HAHN<br>14431 HOLT AVE<br>SANTA ANA, CA 92705 |             |                      | EXAMINER<br>MELLER, MICHAEL V |                  |
|  |             |                      | ART UNIT                      | PAPER NUMBER     |
|  |             |                      | 1655                          |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE             |             | MAIL DATE            | DELIVERY MODE                 |                  |
| 3 MONTHS   |             | 03/27/2007           | PAPER                         |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/821,679

Applicant(s)

TAN, BARRIE

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5,6,10-12,14,15,17,19,20,22,24-30,33,34 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,10-12,14,17,19,20,22,24-29 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15, 30, 33, 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims 5, 6 (drawn to limitations that do not further limit claim 30), 10-12, 14, 17, 19, 20, 22, 24-29, 38 which are drawn to inventions which were nonelected **without** traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The requirement is still deemed to be proper and is therefore made FINAL.

### ***Specification***

The amendment filed 1/5/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendments to claim 30 of "a composition of a 290-390 Dalton MW fraction from an extract of a byproduct solution of *Bixa orellana* seed components", is not supported by the original disclosure since such a range cannot be found anywhere in the original disclosure.

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Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 30, 33, 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the instant specification for "a composition of a 290-390 Dalton MW fraction from an extract of a byproduct solution of *Bixa orellana* seed components". Nothing in the specification supports this phrase. In fact, nowhere in the specification is any molecular weight range supported. Applicant alleges that the support is from a new paragraph that they want to insert in the specification, the declaration by Dr. Barrie Tan filed 1/5/2007 and from Craveiro et al. where applicant

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alleges that they teach different molecular weights of bixins and geranyl geraniols. While this is interesting, it does not provide support for the claimed range. Even if Craveiro teaches that specific molecular weights are known for certain substances (which this examiner is not saying is the case), this in and of itself does not provide adequate support for the claimed molecular weight range. Thus, "a composition of a 290-390 Dalton MW fraction from an extract of a byproduct solution of *Bixa orellana* seed components", finds no support from the instant specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 33, 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Alaux et al. (col. 8, lines 55-end), Levy et al. (abstract, paragraphs, 2, 7, ex. 3), Kapadia et al. (col. 7, lines 55-65) or JP 2001114628 (abstract).

Alaux, Levy and Kapadia each teach an annatto extract. Levy teaches that annatto extracts are obtained from the seeds of *Bixa orellana*. JP teaches an oral agent containing an agent from *Bixa orellana*, thus it also teaches an annatto extract. They all teach oral extracts. Since Alaux teaches an annatto extract then according to Levy, it also comes from *Bixa orellana* seeds. It is inherent to the composition that geranyl geraniols are in the annatto extract as noted by applicants in their own specification, see page 11 and as taught by Levy, see paragraph 6. The specifically claimed ratios of geranyl geraniols are inherently in the annatto compositions since the geranyl geraniols are derived from the annatto extract. The ranges of ratios of the isomers are so broad and clearly encompass the disclosed extracts, since such ratios are so broad. It is also noted that in paragraph 10 of the instant specification that annatto extracts typically contain trans and cis forms of the geranyl geraniols, thus clearly falling within the ratios claimed. The ratios of the geranyl geraniols are also inherent since applicant does not describe any method of extracting the plant. Thus, the same extract as in the references had to have been yielded. Applicant's specification provides only the claimed ratios but no method as to how the claimed ratios were obtained thus leading only one to believe that such ratios are inherently in the extract. The different isomer forms and amounts/ratios of geranyl geraniols are inherent to the annatto extract (*Bixa orellana*).

Applicant argues that "a composition of a 290-390 Dalton MW fraction from an extract of a byproduct solution of *Bixa orellana* seed components", is not taught by the references. Fact is, the same starting material (*Bixa orellana* seed) is used in the references as applicant has done, see Levy et al. who states that annatto extracts are

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obtained from the seeds of *Bixa orellana*, see Levy, page 1, left column, paragraph 2.

Thus, since the same starting material (*Bixa orellana*) is used in the references as applicant has done, the extract in the references will also possess the same molecular weight since such a molecular weight is inherent to the extract. Please note that all of the references teach annatto extracts which as taught by Levy contain geranylgeraniols (see paragraph 6) and norbixin which is also obtained from *Bixa orellana* and which comes from the annatto seed extracts, see paragraph 2 of Levy. It is also clearly stated in paragraph 2 of Levy that annatto extracts contain isoprenoid geranylgeraniols.

In Dr. Tan's declaration filed 1/5/2007, Dr. Tan makes it clear that geranylgeraniols have a molecular weight in the 290-390 dalton range whereas the bixins from the same extract namely annatto extract have a molecular weight ranging 390-425 daltons. While this may or may not be the case, this evidence is not compelling since there is no reference cited to support such ranges and the ranges overlap so even if the ranges were substantiated, they overlap, thus the molecular weight limitation is not a way that applicant can distinguish the geranylgeraniols from the bixins. Further, even if one could distinguish the bixins from the geranylgeraniols, there is nothing in the claim to exclude the bixins since the claims use the term, "comprising", thus more than just the desired MW fraction can be in the claimed composition. Thus, the claims do not distinguish over the cited references.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 30, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alaux et al. (col. 8, lines 55-end), Levy et al. (ex. 3), Kapadia et al. (col. 7, lines 55-65), or JP 2001114628 (abstract) taken with JP 62123113 (abstract), GB 2178662 (page 2, lines 10-15) or WO 89/01740 (claims).

Alaux et al. (col. 8, lines 55-end), Levy et al. (ex. 3), Kapadia et al. (col. 7, lines 55-65) and JP 2001114628 (abstract) each teach what is above.

They do not teach the addition of CO-Q 10 to the composition.

JP 62123113 (abstract), GB 2178662 (page 2, lines 10-15) and WO 89/01740 (claims) all teach that CO Q-10 is known to be used in oral compositions.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In*



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*re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103.  
<[http://www.uspto.gov/web/offices/pac/mpep/documents/2100\\_2144.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm)>

It would have been obvious to one of ordinary skill in the art to use the annatto extract (*Bixa orellana*) and the CO Q-10 together since they are both known individually in the art to be used in oral compositions.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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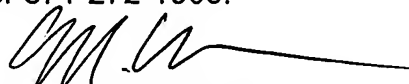
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael V. Meller  
Primary Examiner  
Art Unit 1655